Complete Summary

GUIDELINE TITLE

Guidance on the use of drugs for early thrombolysis in the treatment of acute myocardial infarction.

BIBLIOGRAPHIC SOURCE(S)

National Institute for Clinical Excellence (NICE). Guidance on the use of drugs for early thrombolysis in the treatment of acute myocardial infarction. London (UK): National Institute for Clinical Excellence (NICE); 2002 Oct. 25 p. (Technology appraisal guidance; no. 52).

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Acute myocardial infarction

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Treatment

CLINICAL SPECIALTY

Cardiology
Emergency Medicine
Family Practice
Internal Medicine

INTENDED USERS

Advanced Practice Nurses
Nurses
Patients
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To examine the clinical and cost-effectiveness of available drugs for early thrombolysis in the treatment of acute myocardial infarction (AMI) in hospital and pre-hospital settings

TARGET POPULATION

Patients with acute myocardial infarction (AMI)

INTERVENTIONS AND PRACTICES CONSIDERED

Thrombolytic agents (alteplase, reteplase, streptokinase, or tenecteplase)

MAJOR OUTCOMES CONSIDERED

- Clinical effectiveness
    - Mortality
    - Patency of coronary arteries
    - Left ventricular function
    - Stroke
    - Reinfarction
    - Bleeding
    - Allergy
    - Anaphylaxis
    - Adverse effects
- Cost-effectiveness

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the Liverpool Reviews and Implementation Group (See the "Availability of Companion Documents" field.)

Clinical Effectiveness

Search Strategy

The search incorporated a number of strategies. Search terms for electronic databases included were myocardial infarction/heart infarction and thrombolysis combined with specific drug terms (e.g., alteplase [t-PA], reteplase, streptokinase, tenecteplase, anistreplase, and urokinase.

Electronic searches included the following databases:

- MEDLINE (1980-2001)
- EMBASE (1980-2001)
- Science Citation Index/Web of Science (1988-2001)
- Cochrane Trials Register (2001, 4)
- Health Technology Assessment (HTA) (1992-2001)
- Database of Abstracts of Reviews of effectiveness (DARE) (1998-2001)

Specific search strategies and the number of references retrieved for each search is provided in Appendices III, IV and V of the Assessment Report (see the "Availability of Companion Documents" field).

Searching was limited to English language reports.

Reference lists of included studies and pharmaceutical company submissions were searched to identify other relevant studies. In addition, hand searching of American Heart Journal, Circulation, American Journal of Cardiology, British Medical Journal, European Heart Journal, Heart, Emergency Medicine Journal, International Journal of Cardiology, Journal of the American College of Cardiology, Journal of the American Medical Association, Lancet, New England Journal of Medicine, and Stroke was carried out for the period of January 2001 to January 2002 to identify any newly published papers that might not yet have been indexed in electronic databases.

All the references were exported to Endnote reference database, ISI Research Soft, Cal., USA, version 5.

Inclusion and Exclusion Criteria

The identified citations were assessed for inclusion through two stages and disagreements were settled by discussion at each stage. Two reviewers independently scanned all the titles and abstracts and identified the potentially

relevant articles to be retrieved. Full text copies of the selected papers were obtained and assessed independently by two reviewers for inclusion. Studies were considered eligible for inclusion if they met the following criteria:

Study Design

Randomised controlled trials (RCTs) that include comparison of included drugs and any or all of the listed outcomes.

Interventions

Comparison of currently available intravenous thrombolytic therapies administered in the early stages of acute myocardial infarction (AMI) in the hospital or pre-hospital setting. Drugs included in the review were: tissue plasminogen activator (t-PA), reteplase, streptokinase, and tenecteplase. Studies that examine the use of anistreplase (not currently available) or urokinase (not currently licensed for use in thrombolysis in the United Kingdom) were also identified and used to inform the background of the review but not included in the analysis.

Participants

Patients with recent on-set AMI without contraindications to thrombolytic therapy. Diagnosis of AMI to be made through clinical assessment or electrocardiogram (ECG).

Outcomes

Data on the following outcome measures were included:

- Mortality
- Patency of coronary arteries
- Left ventricular function
- Stroke
- Reinfarction
- Bleeding
- Allergy
- Anaphylaxis

Cost-Effectiveness

Search Strategy

The following databases were searched for English language papers.

- MEDLINE
- EMBASE
- NHS Economic Evaluation Database (NHSEED)
- Database of Abstracts of Reviews of Effectiveness (DARE)
- Science Citation Index/Web of Science
- Cochrane Trials Register
- Health Technology Assessment (HTA)

Search strategies and results of the searches undertaken are presented in Appendix VI of the Assessment Report (see the "Availability of Companion Documents" field).

Inclusion and Exclusion Criteria

Using explicit, predetermined criteria, two reviewers independently identified studies for inclusion in the cost-effectiveness review process. Decisions were compared.

Where there was disagreement, both reviewers discussed the paper together and a final decision was made. The inclusion and exclusion criteria used in the review are presented below.

Inclusion Criteria for Economic Evaluation Papers

- Active comparator (streptokinase, alteplase, reteplase, or tenecteplase)
- Efficacy data primarily based on published drug versus drug randomised controlled clinical trial evidence
- Explicit synthesis of costs and outcomes in a cost effectiveness ratio
- Full economic evaluation
- Primary paper

Exclusion Criteria for Economic Evaluation Papers

- Non-drug comparator (e.g., placebo or conservative therapy) or aspirin, urokinase, anistreplase
- Source of clinical efficacy data from non-randomised clinical trial or not explicitly stated
- No attempt to synthesise costs and benefits
- Letters, editorials, reviews, commentaries or methodological papers

All the references were exported to Endnote reference database, ISI Research Soft, Cal., USA, version 5.

NUMBER OF SOURCE DOCUMENTS

Clinical Effectiveness

A total of 162 references were identified to which the inclusion criteria were applied. Of these, 20 studies reported in 50 articles fulfilled the inclusion criteria.

Cost-Effectiveness

Of the 107 articles assessed, only eight met the quality criteria that led them to be evaluated in detail.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the Liverpool Reviews and Implementation Group (See the "Availability of Companion Documents" field.)

Clinical Effectiveness

Data Extraction

Hospital

Data extraction was carried out by three reviewers. Data were independently extracted by one reviewer and checked by a second into a pre-designed data extraction form.

Data from multiple reports of single trials were extracted onto a single data extraction form.

Pre-hospital

Data for information tables were extracted by one reviewer and checked by a second.

Quality Assessment

Hospital

Three reviewers independently evaluated the included primary studies for methodological quality. This involved methodological assessment for clinical effectiveness based on Centre for Reviews and Dissemination, York, Report 4 (see Appendix VI of the Assessment Report [see the "Availability of Companion Documents" field]). Any discrepancies were resolved through consensus.

Pre-hospital

Since no studies comparing drugs used in the pre-hospital setting were identified, there were no studies to be assessed. Descriptive comment is provided regarding trials that evaluated pre-hospital care.

Cost-Effectiveness

Data Extraction

All cost-effectiveness data was abstracted by a single reviewer and then checked by a second reviewer. Both reviewers are health economists with expertise in economic evaluation. Given that several of the cost-effectiveness papers included in the review incorporated the use of modelling techniques, it was appropriate to extract additional data from these papers.

The data extracted from the published cost-effectiveness analyses were presented in four sections.

Firstly, there is a section on study design where the following information is stated:

- Type of economic evaluation and measure of synthesis
- Intervention
- Study population
- Time period of analysis and extrapolation details

The second section summarises the key cost and cost data sources used in the studies:

- Cost items
- Cost data sources
- Country, currency and year

The third section summarises the range of outcomes and efficacy data sources used in the studies:

- Range of outcomes
- Efficacy data sources
- Utility values and data sources
- Modelling method and data sources

Finally, the fourth section explores the results of the cost-effectiveness studies:

- Cost-effectiveness ratio
- Subgroup analysis and results
- Sensitivity analysis and results
- Authors conclusions

Quality Assessment

The quality assessment of cost-effectiveness analyses was based on the Drummond 10-point checklist. All studies were scored according to the checklist

detailed in Appendix VIII of the Assessment Report (see the "Availability of Companion Documents" field).

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Clinical Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE website. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

In-Hospital Thrombolysis

The Assessment Group's literature review found eight published articles on the cost-effectiveness of thrombolytic agents that met the inclusion criteria for the review of cost effectiveness. All compared streptokinase and alteplase (standard and accelerated) in a hospital setting. Three of the articles reported different aspects of the same cost-effectiveness model. Most studies reported incremental costs per life-year gained, and three also reported incremental cost per quality-adjusted life year (QALY). Most of the studies were based on the effectiveness results of GUSTO-I, in which data on resource use were collected only for USA centres. Consequently the analyses undertaken in Canada, Ireland, and France had to attempt to translate these to settings in other countries.

Pre-Hospital Thrombolysis

No published articles examining the cost effectiveness of different thrombolytic drugs in pre-hospital settings were found.

See Section 4.2 of the original guideline document for a detailed discussion of the cost-effectiveness analysis.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Consultee organizations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

This guidance provides recommendations on the selection of thrombolytic drugs in patients with acute myocardial infarction (AMI). Recommendations are made in relation to the use of the drugs in hospital and pre-hospital settings. The guidance does not compare hospital and pre-hospital models of delivering thrombolysis.

- It is recommended that, in hospital, the choice of thrombolytic drug (alteplase, reteplase, streptokinase, or tenecteplase) should take account of:
    - The likely balance of benefit and harm (for example, stroke) to which each of the thrombolytic agents would expose the individual patient
    - Current United Kingdom clinical practice, in which it is accepted that patients who have previously received streptokinase should not be treated with it again
    - The hospital's arrangements for reducing delays in the administration of thrombolysis
- Where pre-hospital delivery of thrombolytic drugs is considered a beneficial approach as part of an emergency-care pathway for AMI (for example, because of population geography or the accessibility of acute hospital facilities), the practicalities of administering thrombolytic drugs in pre-hospital settings mean that the bolus drugs (reteplase or tenecteplase) are recommended as the preferred option.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of thrombolytic drugs in acute myocardial infarction (MI)

POTENTIAL HARMS

Bleeding complications are the main risks associated with thrombolysis. The most important bleeding complication is haemorrhagic stroke, which occurs in 0.5-1.0%

of patients and is associated with high mortality and long-term disability in survivors. Bleeding may occur at the injection site, in the gastrointestinal tract, or elsewhere. Hypotension may also occur.

For full details of side effects and contraindications, see the Summaries of Product Characteristics, available at http://emc.medicines.org.uk/.

CONTRAINDICATIONS

CONTRAINDICATIONS

Current Contraindications to Thrombolysis

Current contraindications* to treatment are related to risk of bleeding and are divided into absolute and relative:

Absolute Contraindications

- Gastrointestinal (GI) bleeding in the previous month
- History of cerebrovascular disease especially recent events or with any residual disability
- Bleeding disorder or on anticoagulant therapy
- Major surgery, trauma or head injury in previous 3 weeks
- Prolonged cardiopulmonary resuscitation (CPR) (>30 minutes)
- Hypertension (>180 mmHg systolic)
- Aortic dissection
- Acute pancreatitis
- Lung cavitations

Relative Contraindications

- Major hepatic or renal disease
- Non-compressible puncture site
- Known terminal illness
- Recent retinal laser treatment

*As listed in recommendations from the European Society of Cardiology.

Also, in the case of streptokinase, previous allergic reactions to either streptokinase or anistreplase or administration of either drug in the previous 2 years.

For full details of side effects and contraindications, see the Summaries of Product Characteristics, available at http://emc.medicines.org.uk/.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

- National Health Service (NHS) organisations that currently offer or plan to offer treatment for patients with acute myocardial infarction (AMI), including ambulance paramedic services, general practitioners, and all clinicians involved in the care of these patients, should review policies and practices regarding drugs for early thrombolysis in the treatment of patients with AMI to take account of the guidance (see the "Major Recommendations" field).
- Clinical teams involved in the care of patients with AMI should review and revise, if appropriate, any local guidelines or care pathways on early thrombolysis in the treatment of patients with AMI to incorporate the guidance (see the "Major Recommendations" field).
- The Coronary Heart Disease (CHD) Collaborative of the NHS Modernisation Agency is developing approaches to increase the timeliness of care to people with AMI. For more information, see www.modernnhs.nhs.uk/serviceimprovement/1338/4668/ThrombolysisBulletin2.pdf.
- The Myocardial Infarction National Audit Project (MINAP) collects data that enable clinicians to examine the management of patients with AMI within their hospitals in comparison to the standards in the National Service Framework (NSF) for CHD. This national audit includes collection of the following data that are relevant to this guidance:
    - Thrombolytic drug used
    - Reasons for non-administration of thrombolytic treatment
    - Reasons for delay in the administration of thrombolytic treatment
    - Location for the administration of treatment
    - Who made the initial decision for treatment

  For more information on MINAP, see: Birkhead JS, Norris R, Quinn T, Pearson M on behalf of the NSFCHD Steering Group (1999) Acute Myocardial Infarction Core Data Set for Monitoring Standards of Care. London: Royal College of Physicians, or www.rcplondon.ac.uk/college/ceeu/ceeu_ami_home.htm

  The current core dataset appears on the website; the newly revised dataset appears on www.ccad.org.uk.

- The Joint Royal Colleges Ambulance Liaison Committee (JRCALC) and the Ambulance Service Association (ASA) are carrying out a national clinical audit to assess the quality of care by ambulance services for people with AMI. The audit relates to the standards set for ambulance services in the NSF for CHD,

including pre-hospital thrombolysis. This national audit includes collection of the following data that are relevant to this guidance:
    - Thrombolytic drug used
    - Who made the decision to administer thrombolysis
    - Location of the administration of treatment
    - Reasons for non-administration of thrombolytic treatment
- For more information on the national clinical audit of AMI, including pre-hospital thrombolysis, contact the ASA National Clinical Effectiveness Programme or see www.asancep.org.uk.
- Local clinical audits on the care of patients with AMI also could include criteria for the management of AMI based on the national standards, including standards in the NSF. However, given existing national audit programmes no further audit suggestions are made.

IMPLEMENTATION TOOLS

Foreign Language Translations
Patient Resources
Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Institute for Clinical Excellence (NICE). Guidance on the use of drugs for early thrombolysis in the treatment of acute myocardial infarction. London (UK): National Institute for Clinical Excellence (NICE); 2002 Oct. 25 p. (Technology appraisal guidance; no. 52).

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2002 Oct

GUIDELINE DEVELOPER(S)

National Institute for Health and Clinical Excellence - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

Appraisal Committee

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Guidance on the use of drugs for early thrombolysis in the treatment of acute myocardial infarction. Quick reference guide. London (UK): National Institute for Health and Clinical Excellence (NICE); 2002 Dec. 2 p. (Technology appraisal 52). Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.
- Early thrombolysis for the treatment of acute myocardial infarction. Assessment report. NHS R&D HTA Programme; 2002 Apr 11. 158 p. Available in Portable Document Format (PDF) from the NICE Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N0171. 11 Strand, London, WC2N 5HR.

PATIENT RESOURCES

The following is available:

- Guidance on the use of drugs for early thrombolysis in the treatment of acute myocardial infarction. Information for patients. London (UK): National Institute for Health and Clinical Excellence (NICE); 2002 Oct. 8 p. (Technology appraisal 52).

Electronic copies: Available in English and Welsh in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the Department of Health Publications Order Line 0870 1555 455. ref: N0172. 11 Strand, London, WC2N 5HR.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

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